

BILLING CODE 4150-36

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-0263]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before [INSERT DATE 30 DAYS AFTER] DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit your comments to OIRA_submission@omb.eop.gov or via facsimile to (202) 395-5806.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, Sherrette.Funn@hhs.gov or (202) 795-7714. When submitting comments or requesting information, please include the document identifier 0990-New-30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance

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of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Information Collection Request Title: 0990-0263-Extension Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption (Common Rule) form.

Abstract: Assistant Secretary for Health, Office for Human Research Protections is requesting an extension on a currently approved information collection by the Office of Management and Budget, OMB, on the Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption Form. That form is designed to provide a simplified procedure for institutions engaged in research conducted or supported by the Department of Health and Human Services (HHS) to satisfy the requirements of HHS regulations for the protection of human subjects at 45 CFR 46.103. The respondents for this collection are institutions engaged in research involving human subjects where the research is supported by HHS. Institutional use of the form is also relied upon by other federal departments and agencies that have codified or follow the Federal Policy for the Protection of Human Subjects (Common Rule) which is identical to 45 CFR part 46, subpart A.

Likely Respondents: Individuals, business or other for-profit, not for-profit institutions, Federal, State, Local or Tribal Governments.

ESTIMATE ANNUALIZED BURDEN IN HOURS TABLE

Form Name	Number of	Number of	Average	Total
	Respondents	Responses	Burden per	Burden
		per	Response	Hours
		Respondent	(in hours)	
Protection of Human Subjects:	14,000	2	0.5	14,000
Assurance Identification/IRB				
Certification/Declaration of				
Exemption				
Total				14,000

Terry S. Clark,

Asst Information Collection Clearance Officer.

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